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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,165	03/18/2004	Edgardo Costa Maianti	DID1047US	7387

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MINNEAPOLIS, MN 55402

EXAMINER

CRAIG, PAULA L

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/805,165

Applicant(s)

MAIANTI ET AL.

Examiner

Paula L. Craig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 01 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/21/2006.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The rejections of Claims 6, 7, and 9 under 35 U.S.C. 102(b) over Raible are maintained. In addition to the heat exchanger, oxygenator, and arterial blood filter, as described in the prior Office Action mailed June 1, 2006, Raible teaches a top portion of the housing defining the blood reservoir (the blood reservoir is reservoir 111, which is located at the top of the housing, Figs. 8 and 8a, col. 12, lines 6-42). Raible teaches the bottom portion of the housing defining the blood pump (blood pump includes the pump impeller 40a having helical vanes 94a, as well as the shaft, engagement structure 48, and motor/drive component 14, which includes base 13 and is located at the bottom portion of the housing; Figs. 1-2 and 8-8a, col. 5, line 18 to col. 10, col. 12, lines 6-42).
2. For Claims 1-5, 8, and 10, Applicant's arguments in the response filed November 1, 2006 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejections of Claims 6, 7, and 9 under 35 U.S.C. 102(b) as being anticipated by Raible (5,770,149) are maintained for the reasons of record, as well as the reasons given above in paragraph 1.

Claim Rejections - 35 USC § 103

5. Claims 1, 2, 4, 5, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raible (5,770,149) in view of U.S. Patent No. 5,039,482 to Panzani et al.

6. For Claim 1, Raible '149 teaches an integrated device for oxygenating and filtering blood through an extracorporeal blood circuit, a reservoir, a blood pump, a heat exchanger, an oxygenator, an arterial blood filter, and a monolithic housing, as described in the prior office action mailed June 1, 2006. Raible does not teach the blood inlet being located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger. Applicant's specification does not disclose that having the blood inlet located below the blood outlet serves any stated purpose or solves any particular problem. In addition, a blood inlet being located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger is well known in the art. Panzani confirms this and teaches an integrated device for oxygenating and filtering blood through an extracorporeal blood circuit, having a reservoir, a blood pump, a heat exchanger, an oxygenator, and a filter (Figure, col. 1, lines 5-21, col. 2, line 16 to col. 3, line 20). Panzani teaches the heat exchanger having a blood inlet located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger (heat exchanger is heat exchanger 15, blood inlet is blood inlet 22, outlet is lower end of oxygenator 14, Figure, col. 3, lines 1-10). Panzani teaches that this arrangement provides a compact versatile structure and reduces connecting lines to

facilitate installation and operation of the device (col. 3, lines 64-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Raible '149 to include a blood inlet located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger, as taught by Panzani, to provide a compact versatile structure and reduce connecting lines to facilitate installation and operation, as taught by Panzani.

7. For Claim 2, Raible '149 teaches the blood pump being a centrifugal pump (Figs. 3 and 8, col. 10, line 38 to col. 12, line 52).

8. For Claim 4, Raible '149 teaches the blood reservoir including a venous reservoir and a cardiectomy reservoir (Figs. 8-8a and col. 12, lines 6-35).

9. For Claims 5 and 10, Raible or Raible/Panzani teach all the limitations of Claims 4 and 9, as described above in paragraphs 1 and 8. Raible '149 does not teach the housing including connection means for allowing removable connection of the first portion. However, removable reservoirs are well known in the art. Panzani confirms this and teaches a monolithic housing having a connection means for allowing removable connection of the first portion (col. 2, lines 48-52, col. 3, lines 56-64).

Panzani teaches that the removable reservoir is useful in post operative care to recover blood from drainages and the like (col. 3, lines 56-64). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Raible '149 to include the housing having a connection means for allowing removable connection of the first portion, as taught by Panzani, to recover blood from drainages during post operative care, as taught by Panzani.

10. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raible '149 in view of Panzani, and further in view of Izraelev (5,924,848).

11. For Claims 3 and 8, Raible or Raible/Panzani teach all the limitations of Claims 2 and 7, as described above in paragraphs 1 and 7. Raible '149 teaches the centrifugal pump having an axis, and the centrifugal pump being positioned within the monolithic housing (Figs. 3 and 8a). Raible '149 does not teach the axis of the centrifugal pump being horizontal. Izraelev teaches a centrifugal pump for pumping human blood in which the axis of the pump may be horizontal or vertical (Figs. 1-3 and col. 3, lines 52-59). The pump of Izraelev is designed to be stable when the direction of the pump's axis of rotation is changed because the position of the housing is changed (col. 3, lines 52-59). It would have been obvious to one of ordinary skill in the art to modify Raible or Raible/Panzani to include the axis of the centrifugal pump being vertical or horizontal, as taught by Izraelev, to provide for flexibility in positioning the pump, as taught by Izraelev.

Double Patenting

12. The rejections of Claims 1, 2, 4, 5, 6, 7, 9, and 10 over Claims 1-5 of U.S. Patent No. 6,723,283 to Ghelli, and the provisional rejections of Claims 1-10 over copending U.S. Patent Application No. 10/614,722 to Maianti, are maintained for the reasons of record. Although the response filed November 1, 2006 indicated that terminal

disclaimers over Ghelli '283 and Maianti '722 were being filed, no such terminal disclaimers have been received.

Conclusion

13. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on 8:30AM-4:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

